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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,163	12/21/2001	Audra L. Stinchcomb	ACP-0001	6957

23550 7590 09/10/2004

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,163	STINCHCOMB, AUDRA L.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8-10, 29, 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6, 8-10, 29, 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/08/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's IDS, filed 01/08/2004; and request under 1.114, amendment and request for extension of time, all filed 07/06/2004.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/06/2004 has been entered.

Claims 2-6, 8-10, 29, and 30 are included in the prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because they depend on

claim 29 that has the closed language "consisting essentially of" that does not permit the addition of other ingredients to the composition, such as the flowable gel of claim 4 or the opiate of claim 10. Clarification is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 6, 8, 9, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/53917 ('917).

WO '917 disclosed a method for using cannabidiol in subjects who have been exposed to cancer chemotherapy or who have HIV (page 10, lines 4-6, 34; page 11, lines 19-21; page 20, lines 32-34; page 33, claim 14). The cannabidiol can be administered transdermally or topically (page 23, lines 17-20). The symptoms of chemotherapy are inherent for a specific chemotherapeutic agent.

The limitations of claims 6, 8, 9, 29 and 30 are met by WO '917.

6. Claims 2-6, 8-9, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,328,992 ('992).

US '992 disclosed transdermal structure for delivering cannabis for the treatment of nausea and pain associated with cancer chemotherapy and wasting associated with AIDS, that reads on claims 1 and 6 (abstract; col.1, lines 24-30). Cannabis means any one or more or mixture of compounds or chemical components including cannabidiol, that reads on claims 1 and 7 (col.2, lines 47-53; col.7, lines 54-58). The transdermal structure comprises patches, bandages or covering, that reads on claims 8 and 9 (col.1, lines 58-60). The patch is occlusive and comprises backing layer; rate controlling membrane; reservoir positioned between the backing and the rate controlling membrane and comprises the active agent in a suitable carrier; and an adhesive means, that reads on claims 2, 3, and 5 (col.2, lines 6-10, 21-24; col.3, lines4-8, 25-28, 49-51, 64-67; col.4, lines 66-67; col.5, line 1). The suitable carrier includes gel, that reads on claim 4 (col.3, lines 37-45).

The limitations of claims 1-6,8, 9, 29 and 30 are met by the US '992 reference.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '917 or US '992 in view of PGPB 2003/0158191 ('191).

The teachings WO '917 and US '992 are discussed under 102 rejection above.

The references do not teach the inclusion of opiate with the transdermal delivery of cannabis derivatives.

PGPB '191 teaches a combination of cannabis derivatives delivered transdermally with other active agents including morphine page 2, 0012; page 10, 0214; page 14, 0356; page 15, 0359, 0362). The reference teaches that the combination therapy may allow for increased efficacy and potentially reduces side effects (page 16, 0370).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cannabidiol delivered transdermally as taught by any of WO '917 or US '992 and add opiate in the transdermal system as taught by PGPB '191, motivated by the teaching of PGPB '191 that the combination therapy may allow for facilitating increased efficacy and potentially reduces side effects, with reasonable expectation of having a device that delivers cannabis derivatives and opiate with increased efficacy and reduced side effects.

9. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '917 in view of US '992.

The teachings of WO '917 and US '992 are discussed under 102 rejection above. However, WO '917 does not teach structure of the transdermal device used to deliver the cannabidiol.

The occlusive transdermal device disclosed by US '992 is advantageous as it allows controlled delivery of the cannabinoid over a predetermined period of time such that plasma level of cannabinoid may be controlled in a safe, convenient and effective manner for the patient (col1, lines 58-65).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal delivery of cannabidiol as disclosed by WO '917, and select the occlusive delivery device disclosed by US '992, motivated by the teachings of US '992 that the occlusive transdermal device is advantageous as it allows controlled delivery of the cannabinoid over a predetermined period of time such that plasma level of cannabinoid may be controlled in a safe, convenient and effective manner for the patient, with reasonable expectation of having an occlusive transdermal device that delivers cannabidiol in safe, convenient, effective and controlled manner to the patients in need of such treatment.

Response to Arguments

10. Applicant's arguments filed 07/06/2004 have been fully considered but they are not persuasive.

Applicant traverses the rejection of the claims as being anticipated by US '992 by arguing that US '992 does not teach transdermal delivery of a composition consisting

essentially of CBD, but teaches administration of a mixture of cannabinoids. Further, the subject matter of the claims under consideration, as amended, is not anticipated by and could not have been obvious over US '992 alone or in combination with US '191 because they teach the administration of the mixture of cannabinoids, and different compounds can have different effect on transdermal delivery of other compounds and one can not predict with reasonable degree of success how different compounds will behave when administered alone based on how they behave when administered in combination.

In response to the above arguments, the examiner position is that the claims as amended still anticipated by US '992 because the reference disclosed the transdermal administration of cannabinoid mixture including cannabidiol (CBD). The expression "consisting essentially of" does not exclude the presence of other components that does not materially alter the composition, and the "cannabidiol" encompasses more than one compound as disclosed by applicant on page 7 of the present specification. The reference choice to combine CBD with other cannabinoids does not make the present claims patentable. The art recognized the transdermal administration of composition comprising CBD to relieve the symptoms associated with cancer chemotherapy and wasting associated with HIV infection. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699

F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonable suggested to one having ordinary skill in the art, including nonpreferred embodiments. US '191 is relied upon for teaching of administration of a combination of the cannabinoid with opioid.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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Isis Ghali

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PATENT EXA...